

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NEW MEXICO UNITED FOOD AND
COMMERCIAL WORKERS UNION'S AND
EMPLOYERS' HEALTH AND WELFARE
TRUST FUND, on behalf of itself and all others
similarly situated,

Plaintiff,

v.

PURDUE PHARMA L.P.,
PURDUE PHARMA, INC.,
THE PURDUE FREDERICK COMPANY, INC.
d/b/a THE PURDUE FREDERICK COMPANY,
P.F. LABORATORIES, INC.,
ABBOTT LABORATORIES,
ABBOTT LABORATORIES, INC.,
MICHAEL FRIEDMAN,
HOWARD R. UDELL,
PAUL D. GOLDENHEIM, JOHN DOE Nos. 1
through 20, and JANE DOE Nos. 1 through 20,

Defendants.

Civil Action No. 07-cv-06916-JGK

**ANSWER OF THE PURDUE FREDERICK
COMPANY INC. TO CLASS ACTION COMPLAINT**

The Purdue Frederick Company Inc. ("PF"), doing business as The Purdue Frederick
Company, in answer to plaintiff's Class Action Complaint ("Complaint"),¹ states as follows:

¹ PF states that this answer is filed solely on behalf of PF. Other defendants in this lawsuit include Abbott Laboratories and Abbott Laboratories, Inc. (the "Abbott defendants"). PF does not and cannot speak on behalf of the Abbott defendants, and the answers pertain solely to the answering defendant, and not to the Abbott defendants. Plaintiff's use of the word

(Cont'd on following page)

AS TO THE ALLEGED NATURE OF THE ACTION

1. PF denies the allegations contained in paragraph 1 of the Complaint, except admits that OxyContin® Tablets ("OxyContin") is a prescription medication, and is a controlled-release oral form of oxycodone hydrochloride.

2. PF states that paragraph 2 of the Complaint contains plaintiff's characterization of its claims, to which no answer is required. To the extent an answer is required, PF denies the allegations contained therein, except admits that plaintiff purports to bring this action as a class action, and to define a putative class, but denies that plaintiff's claims are the proper subject of class certification.

3. PF states that paragraph 3 of the Complaint contains Plaintiff's characterization of its claims, to which no answer is required. To the extent an answer is required, PF denies the allegations contained therein, except admits that certain of the Purdue defendants have researched, designed, formulated, compounded, tested, manufactured, produced, processed, assembled, inspected, labeled, packaged, distributed, marketed, promoted, or advertised OxyContin. PF further admits that plaintiff purports to bring this action as a class action, and to define a putative class, but denies that plaintiff's claims are the proper subject of class certification and specifically denies that plaintiff (and the putative class members) is entitled to any relief whatsoever.

(Cont'd from preceding page)

"defendants" in its allegations do not signal a response by this defendant on behalf of all defendants.

4. PF denies the allegations contained in paragraph 4 of the Complaint, except admits that plea agreements were signed by PF, Howard R. Udell, Paul D. Goldenheim and Michael Friedman in the United States District Court for the Western District of Virginia, Case No. 1:07CR00029, which plea agreements speak for themselves as to their content, and pursuant to which plea agreements PF entered a plea of guilty to 21 U.S.C. §§ 331(a) and 333(a)(2), and Howard R. Udell, Paul D. Goldenheim, and Michael Friedman each entered a plea of guilty to 21 U.S.C. §§ 331(a) and 333(a)(1) on or about May 10, 2007. PF further states that OxyContin is, and generally has been, marketed in accordance with the FDA-approved professional prescribing information ("package insert") for OxyContin, which speaks for itself as to its content, except that, prior to July 2001, some employees of certain of the Purdue defendants made, or told other employees of certain of the Purdue defendants to make, certain statements about OxyContin to some healthcare professionals that were inconsistent with the package insert for OxyContin and the express warnings it contained about risks associated with the medicine, which statements violated written company policies requiring adherence to the prescribing information.

AS TO ALLEGED PARTIES

5. PF denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 5 of the Complaint, except denies the allegation contained therein that plaintiff was "injured by the conduct alleged herein."

6. PF states that no response is required to plaintiff's definition of "Purdue Defendants" and "Purdue" contained in paragraph 6 of the Complaint. PF denies the remaining allegations contained in paragraph 6, except admits that Purdue Pharma L.P. was and is a Delaware limited partnership with its principal place of business located at One Stamford Forum,

201 Tresser Boulevard, Stamford, Connecticut, that Purdue Pharma L.P. is the successor-in-interest to The Purdue Pharma Company, and that, at relevant times, Purdue Pharma L.P. was engaged in the business of designing, testing, manufacturing, labeling, marketing, advertising, promoting, distributing or selling OxyContin.

7. PF denies the allegations contained in paragraph 7 of the Complaint, except admits that Purdue Pharma Inc. was and is a New York corporation with its principal place of business located in Stamford, Connecticut, and that Purdue Pharma Inc. is the general partner of Purdue Pharma L.P.

8. PF denies the allegations contained in paragraph 8 of the Complaint, except admits that PF was and is a New York corporation with its principal place of business located in Stamford, Connecticut, and that PF is in the business of designing, testing, manufacturing, labeling, marketing, advertising, promoting, distributing or selling OxyContin.

9. PF denies the allegations contained in paragraph 9 of the Complaint, except admits that The P.F. Laboratories, Inc. is a New Jersey corporation with its principal place of business located at 700 Union Boulevard, Totowa, New Jersey; that The P.F. Laboratories, Inc. was, at relevant times, engaged in the business of manufacturing OxyContin in the State of New Jersey on behalf of an associated company; that, as part of the manufacturing process, The P.F. Laboratories, Inc. has conducted certain quality control tests on the product as regulated by the FDA; that The P.F. Laboratories, Inc. has affixed to the product those labels that were provided to it by the associated company through a third party printing company; and that The P.F. Laboratories, Inc. has delivered the manufactured product on behalf and at the direction of the associated company.

10. In response to paragraph 10 of the Complaint, PF admits that, at relevant times, one or more of the Purdue defendants owned the patents covering OxyContin.

11. PF denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first sentence of paragraph 11 of the Complaint, except states that no response is required to plaintiff's definition of the "Abbott Defendants" or "Abbott" contained therein. PF denies the remaining allegations contained in paragraph 11, except admits that Abbott Laboratories has provided limited and defined promotional assistance in the marketing of OxyContin.

12. PF denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the first sentence of paragraph 12 of the Complaint. PF denies the remaining allegations contained in paragraph 12, except admits that Abbott Laboratories, Inc. has provided limited and defined promotional assistance in the marketing of OxyContin.

13. In response to paragraph 13 of the Complaint, PF admits that, at relevant times, the Abbott defendants have provided limited and defined promotional assistance in the marketing of OxyContin throughout the United States, pursuant to an agreement between Purdue Pharma L.P. and Abbott Laboratories, dated on or about January 1, 1996 (the "Co-Promotion Agreement").

14. PF denies the allegations contained in paragraph 14 of the Complaint, except admits that Michael Friedman joined The Purdue Frederick Company in 1985 as Vice President and Assistant to the President and Chairman, that he was appointed Group Vice President of The Purdue Frederick Company in 1988 and was appointed Group Vice President of Purdue Pharma

L.P. in 1994, that he was appointed Executive President and Chief Operating Officer of The Purdue Frederick Company and Purdue Pharma L.P. in 1999, and that he was President and Chief Executive Officer of PF and Purdue Pharma L.P. from 2003 until June 8, 2007.

15. PF denies the allegations contained in paragraph 15 of the Complaint, except admits that Howard R. Udell is a resident of Westport, Connecticut, that he joined The Purdue Frederick Company in 1977 as General Counsel, that he was appointed Group Vice President and General Counsel of The Purdue Frederick Company in 1989 and Purdue Pharma L.P. in 1992, that he was appointed Executive Vice President and General Legal Counsel of The Purdue Frederick Company and Purdue Pharma L.P. in 1999, and that he is currently the Executive Vice President and Chief Legal Officer of PF and Purdue Pharma L.P., and has held these titles since 2003.

16. PF denies the allegations contained in paragraph 16 of the Complaint except admits, upon information and belief, that Paul D. Goldenheim is a resident of Wilton, Connecticut, and further admits that Paul D. Goldenheim joined The Purdue Frederick Company in 1985 as Medical Director, that he was appointed Vice President and Medical Director of The Purdue Frederick Company in 1986, that he was appointed Vice President of Scientific and Medical Affairs of The Purdue Frederick Company and Executive Director of Purdue Frederick Research Center in 1988, that he was appointed Group Vice President of Scientific and Medical Affairs of The Purdue Frederick Company in 1989, that he was appointed Executive Vice President of Medical and Scientific Affairs of The Purdue Frederick Company and Purdue Pharma L.P. in 1999, that he was appointed Executive Vice President of Worldwide Research & Development of The Purdue Frederick Company and Purdue Pharma L.P. in 2000, that he was appointed Executive Vice President of Worldwide Research & Development and Chief Scientific

Officer of The Purdue Frederick Company and Purdue Pharma L.P. in 2003, and that he ceased to work for The Purdue Frederick Company and Purdue Pharma L.P. in 2004.

17. PF denies each and every allegation contained in paragraph 17 of the Complaint.

AS TO JURISDICTION

18. PF states that paragraph 18 of the Complaint asserts legal conclusions and plaintiff's characterization of its claims, to which no answer is required. To the extent an answer is required, PF denies each and every allegation contained therein.

19. PF states that paragraph 19 of the Complaint asserts legal conclusions to which no answer is required. To the extent an answer is required, PF denies each and every allegation contained therein.

20. PF states that paragraph 20 of the Complaint asserts legal conclusions to which no answer is required. To the extent an answer is required, PF denies each and every allegation contained therein.

AS TO FACTUAL ALLEGATIONS

21. PF denies the allegations contained in paragraph 21 of the Complaint, except admits that OxyContin is a controlled release oral formulation Schedule II prescription medication, and that the active opioid ingredient in OxyContin is oxycodone hydrochloride, an opioid agonist. PF further admits that OxyContin was approved by the FDA in December 1995, and that the original FDA-approved package insert for OxyContin stated that OxyContin is

"indicated for the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days."

22. PF denies the allegations contained in paragraph 22 of the Complaint, except admits that certain of the Purdue defendants developed or patented OxyContin, and that OxyContin was approved for sale by the FDA in December 1995.

23. PF denies the allegations contained in paragraph 23 of the Complaint, except admits that Purdue Pharma L.P. and Abbott Laboratories entered into the Co-Promotion Agreement on or about January 1, 1996.

24. PF denies the allegations contained in paragraph 24 of the Complaint, except admits that OxyContin was available initially in 10 mg, 20mg, and 40 mg tablets, that in 1997, OxyContin 80 mg tablets became available, and that in July 2000, OxyContin 160 mg tablets became available, but states that in May 2001, shipments of 160 mg tablets were suspended.

25. PF denies the allegations contained in paragraph 25 of the Complaint, except admits that OxyContin is a Schedule II prescription medication and controlled substance as defined in the Controlled Substances Act, 21 U.S.C. § 801, *et seq.*, and refers to the applicable federal and state statutes and regulations for the definitions and characteristics of, and procedures for handling, Schedule II controlled substances.

26. PF denies the allegations contained in paragraph 26 of the Complaint, except admits that OxyContin is a controlled-release prescription medication, and that OxyContin is normally taken every twelve hours and that many shorter-acting medications must be taken more frequently. PF further admits that some strengths of OxyContin contain more oxycodone than

many immediate release formulations, but state that the oxycodone in OxyContin is released over time if the tablet is taken orally intact.

27. PF denies the allegations contained in paragraph 27 of the Complaint, except admits that, at relevant times, certain of the Purdue defendants designed, tested, manufactured, advertised, promoted, distributed or sold OxyContin, a prescription pain medication.

28. PF denies the allegations contained in the first sentence of paragraph 28 of the Complaint, except admits that OxyContin was approved by the FDA in December 1995, and that sales of OxyContin thereafter increased for certain years as compared to prior years. PF denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the second sentence of paragraph 28, except admits that net sales of OxyContin in the United States in the year 2000 exceeded six hundred million dollars (\$600,000,000), resulting from over three million (3,000,000) prescriptions, and that sales for OxyContin in 2003 exceeded one billion dollars (\$1,000,000,000) with the number of prescriptions written in that year being in excess of six million (6,000,000).

29. PF denies the allegations contained in paragraph 29 of the Complaint, except states that OxyContin is, and generally has been, marketed in accordance with the package insert for OxyContin, except that, prior to July 2001, some employees of certain of the Purdue defendants made, or told other employees of certain of the Purdue defendants to make, certain statements about OxyContin to some healthcare professionals that were inconsistent with the package insert for OxyContin and the express warnings it contained about risks associated with the medicine, which statements violated written company policies requiring adherence to the prescribing information.

30. PF denies the allegations contained in paragraph 30 of the Complaint, except admits that OxyContin was promoted to physicians, including to primary care physicians. PF further admits that promotional materials for OxyContin may have included language such as "to start with," "to stay with," "the easy way" or "the hard way," and states that any promotional materials speak for themselves as to their content.

31. PF denies the allegations contained in paragraph 31 of the Complaint, except admits that OxyContin has been prescribed by physicians to patients with various non-cancer medical conditions on numerous occasions in addition to patients with cancer, and states that OxyContin is, and generally has been, marketed in accordance with the FDA-approved package insert for OxyContin, which speaks for itself as to its content, except that, prior to July 2001, some employees of certain of the Purdue defendants made, or told other employees of certain of the Purdue defendants to make, certain statements about OxyContin to some healthcare professionals that were inconsistent with the package insert for OxyContin and the express warnings it contained about risks associated with the medicine, which statements violated written company policies requiring adherence to the prescribing information.

32. PF denies the allegations contained in paragraph 32 of the Complaint, except admits that Purdue Pharma L.P. received a letter dated May 11, 2000 from the FDA, which letter, as well as the advertisement which was the subject thereof, speak for themselves as to their content. PF further states that, although Purdue Pharma L.P. disagreed with the FDA reviewer's opinion regarding said advertisement, Purdue Pharma L.P. voluntarily cancelled further publication of said advertisement.

33. PF denies each and every allegation contained in paragraph 33 of the Complaint, except admits that OxyContin has been prescribed by physicians to patients with various non-cancer medical conditions on numerous occasions in addition to patients with cancer, and states that OxyContin is, and generally has been, marketed in accordance with the FDA-approved package insert for OxyContin, which speaks for itself as to its content, except that, prior to July 2001, some employees of certain of the Purdue defendants made, or told other employees of certain of the Purdue defendants to make, certain statements about OxyContin to some healthcare professionals that were inconsistent with the package insert for OxyContin and the express warnings it contained about risks associated with the medicine, which statements violated written company policies requiring adherence to the prescribing information.

34. PF denies the allegations contained in paragraph 34 of the Complaint, except admits that certain promotional videos were sent and/or delivered by sales representatives of certain of the Purdue defendants to certain healthcare professionals in 1999 and 2001, that certain videos distributed in 1999 were not submitted to the FDA for approval, and that certain videos distributed in 2001 were submitted to the FDA, and states that any determinations made by the FDA in connection therewith speak for themselves as to their content.

35. PF denies the allegations contained in paragraph 35 of the Complaint, except states that Purdue Pharma L.P. has sponsored seminars on pain management in certain locations to educate some health care professionals on proper pain management, and evaluated and selected some professionals from the attendees for the purpose of teaching and training certain others in appropriate pain management.

36. PF denies the allegations contained in paragraph 36 of the Complaint, except admits that Purdue Pharma L.P. maintains an Internet site at <http://www.partnersagainstpain.com>, which speaks for itself as to its content.

37. PF denies the allegations contained in paragraph 37 of the Complaint, except admits that certain of the Purdue defendants used Patient Starter Cards between 1998 and 2001, that the Patient Starter Cards were distributed to physicians by sales representatives, that physicians decided which patients would receive Patient Starter Cards, and that the Patient Starter Cards could be redeemed for a specified number of prescription tablets. PF further admits that in April 1998, each sales representative was given five binders, each containing five cards (for a total of twenty-five cards) to distribute to physicians, and that each card was redeemable by a patient for a thirty-day supply of OxyContin and OxyIR® ("OxyIR"). PF further admits that in January 1999, each sales representative received five binders, each containing five cards (for a total of twenty-five cards) to distribute to physicians, and that each card was redeemable by a physician for a thirty-day supply of OxyContin and OxyIR. PF further admits that, for the nine months from April through December 2000, each sales representative received ten cards per month (for a total of ninety cards) to distribute to physicians, and that each card was redeemable by a patient for a seven-day supply of OxyContin and OxyIR, and that in July 2001, each sales representative received ten cards to distribute to physicians, and that each card was redeemable by a patient for a seven day supply of OxyContin. PF further states that each of the foregoing cards was intended to be redeemable by a patient only if the patient's physician exercised his or her independent medical judgment, based on his or her knowledge and experience, to deem the medication appropriate for the patient and to give the card to the patient

for use of the medication by that patient. PF further admits that approximately 34,000 coupons had been redeemed nationally by the time the package insert for OxyContin changed in 2001.

38. PF denies each and every allegation contained in paragraph 38 of the Complaint.

39. PF denies each and every allegation contained in paragraph 39 of the Complaint.

40. PF denies the allegations contained in paragraph 40 of the Complaint, except admits that OxyContin has become a widely prescribed medication for the treatment of moderate to severe pain. PF denies that the acceptance of OxyContin for this purpose by the medical community has been as a result of "aggressive marketing tactics." Rather, OxyContin has become accepted by the medical community for the relief of moderate to severe pain because it has been found to be safe and effective for that purpose.

41. PF denies each and every allegation contained in paragraph 41 of the Complaint.

42. PF denies the allegations contained in paragraph 42 of the Complaint, except admits that OxyContin, like any prescription medication, can be abused by a person taking or using it contrary to the instructions for proper use, and that OxyContin has been abused by some persons by their crushing and/or dissolving the product.

43. PF denies the allegations contained in paragraph 43 of the Complaint, except states that efforts are ongoing to develop an oxycodone formulation so as to reduce the potential for abuse by persons taking or using OxyContin contrary to the instructions for its proper use.

PF further states that the FDA requires rigorous proof of the safety and efficacy of such reformulation for its intended use, including extensive clinical trials in human subjects, before approval of a New Drug Application for the reformulated product.

44. PF denies the allegations contained in paragraph 44 of the Complaint, except admits that the OxyContin formulation does not include an antagonist. PF states that efforts are ongoing to develop an oxycodone formulation so as to reduce the potential for abuse by persons taking or using OxyContin contrary to the instructions for its proper use. PF further states that the FDA requires rigorous proof of the safety and efficacy of such reformulation for its intended use, including extensive clinical trials in human subjects, before the approval of a New Drug Application for the reformulated product.

45. PF denies each and every allegation contained in the first sentence of paragraph 45 of the Complaint. PF denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in the second sentence of paragraph 45 of the Complaint.

46. PF denies the allegations contained in paragraph 46 of the Complaint, except admits that the product labeling for OxyContin has contained a boxed warning since July, 2001, the text of which states as follows:

“WARNING:

OxyContin is an opioid agonist and a Schedule II controlled substance with an abuse liability similar to morphine.

Oxycodone can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing OxyContin in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

OxyContin Tablets are a controlled-release oral formulation of oxycodone hydrochloride indicated for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

OxyContin Tablets are NOT intended for use as a prn analgesic.

OxyContin 80 mg and 160 mg Tablets ARE FOR USE IN OPIOID TOLERANT PATIENTS ONLY. These tablet strengths may cause fatal respiratory depression when administered to patients not previously exposed to opioids.

OxyContin® (oxycodone hydrochloride controlled-release) TABLETS ARE TO BE SWALLOWED WHOLE AND ARE NOT TO BE BROKEN, CHEWED, OR CRUSHED. TAKING BROKEN, CHEWED, OR CRUSHED OxyContin® TABLETS LEADS TO RAPID RELEASE AND ABSORPTION OF A POTENTIALLY FATAL DOSE OF OXYCODONE.”

47. PF denies the allegations contained in paragraph 47 of the Complaint, except admits that in July 2001, the Connecticut Attorney General sent a letter to Purdue Pharma L.P., which letter speaks for itself as to its content. PF further admits that Purdue Pharma L.P. responded to this letter in August 2001, and states that such response speaks for itself as to its content. PF states that efforts are ongoing to develop an oxycodone formulation so as to reduce the potential for abuse by persons taking or using OxyContin contrary to the instructions for its proper use. PF further states that the FDA requires rigorous proof of the safety and efficacy of such reformulation for its intended use, including extensive clinical trials in human subjects, before approval of a New Drug Application for the reformulated product.

48. PF denies each and every allegation contained in paragraph 48 of the Complaint.

49. PF states that no response is required to the last sentence of paragraph 49 of the Complaint, as it does not contain an averment of fact to which an answer is required. PF denies the remaining allegations contained in paragraph 49, except admits that, following an investigation by the United States Attorney's Office for the Western District of Virginia and the United States Department of Justice Office of Consumer Litigation, a plea agreement was signed

by PF in Case No. 1:07CR00029, which plea agreement speaks for itself as to its content, and pursuant to which plea agreement PF entered a plea of guilty to 21 U.S.C. §§ 331(a) and 333(a)(2) on or about May 10, 2007 and agreed to pay over \$600,000,000 (six hundred million dollars) in criminal fines and civil penalties. PF further admits that on or about May 10, 2007, an Information was filed as Attachment F to the plea agreement, which speaks for itself as to its content.

50. PF states that no response is required to the last sentence of paragraph 50 of the Complaint, as it does not contain an averment of fact to which an answer is required. PF denies the remaining allegations contained in paragraph 50, except admits that plea agreements were signed by Howard R. Udell, Michael Friedman, and Paul D. Goldenheim on or about May 10, 2007 in Case No. 1:07CR00029, which plea agreements speak for themselves as to their content, and pursuant to which plea agreements each of these signatories entered a plea of guilty to 21 U.S.C. §§ 331(a) and 333(a)(1) and collectively agreed to pay more than \$34,000,000 (thirty-four million dollars) to the Virginia Medicaid Fraud Unit's Program Income Fund.

51. In response to paragraph 51 of the Complaint, PF states that the plea agreement signed by PF in Case No. 1:07CR00029 on or about May 10, 2007 speaks for itself as to its content.

52. PF denies the allegations contained in paragraph 52 of the Complaint, except states that the plea agreement signed by PF in Case No. 1:07CR00029 on or about May 10, 2007 speaks for itself as to its content.

53. PF denies the allegations contained in paragraph 53 of the Complaint, except states that the plea agreement signed by PF in Case No. 1:07CR00029 on or about May 10, 2007,

and the documents attached thereto, including the Agreed Statement of Facts, speak for themselves as to their content.

54. PF denies the allegations contained in paragraph 54 of the Complaint, except admits that the Agreed Statement of Facts states: "[f]rom January 1996 through June 30, 2001, PURDUE[, as defined therein,] received approximately \$2.8 billion in revenue from the sale of OxyContin."

55. PF denies the allegations contained in paragraph 55 of the Complaint, except admits that, as part of the plea agreement it signed on or about May 10, 2007, PF agreed to "accept responsibility for its conduct" and to "not deny that it committed the crime to which it has plead guilty," and states that the plea agreement speaks for itself as to its content.

56. PF denies the allegations contained in paragraph 56 of the Complaint, except admits that a Corporate Integrity Agreement was signed by Purdue Pharma L.P. on or about May 7, 2007 and by the United States Department of Health and Human Services on or about May 8, 2007, and states that the Corporate Integrity Statement, which was attached as Attachment E to the plea agreement signed by PF on or about May 10, 2007, speaks for itself as to its content.

57. In response to the allegations contained in paragraph 57 of the Complaint, PF admits that a press release was issued from the United States Attorney's Office for the Western District of Virginia on or about May 10, 2007, which speaks for itself as to its content.

58. In response to the allegations contained in paragraph 58 of the Complaint, PF admits that the press release issued from the United States Attorney's Office for the Western

District of Virginia on or about May 10, 2007 included statements by Assistant Attorney General Peter D. Keisler, and states that the press release speaks for itself as to its content.

59. In response to the allegations contained in paragraph 59 of the Complaint, PF admits that the press release issued from the United States Attorney's Office for the Western District of Virginia on or about May 10, 2007 included statements by the Inspector General for the U.S. Department of Health and Human Services, Daniel R. Levinson, and states that the press release speaks for itself as to its content.

60. In response to the allegations contained in paragraph 60 of the Complaint, PF admits that the press release issued from the United States Attorney's Office for the Western District of Virginia on or about May 10, 2007 included statements by the Inspector General for the U.S. Department of Labor, but denies plaintiff's characterization of such statements, and states that the press release speaks for itself as to its content.

61. PF denies the allegations contained in paragraph 61 of the Complaint, except admits that the plea agreements pertain to conduct only through June 30, 2001, and that the product labeling for OxyContin has contained a boxed warning since July, 2001.

62. PF denies the allegations contained in paragraph 62 of the Complaint, except admits that Purdue Pharma L.P. received a letter dated January 17, 2003 from the FDA which letter, as well as the advertisements which were the subject thereof, speak for themselves as to their content.

63. PF denies the allegations contained in paragraph 63 of the Complaint, except admits that on February 12, 2002, Paul D. Goldenheim provided testimony to the Senate

Committee on Health, Education, Labor and Pensions, which speaks for itself as to its content.

PF further admits that on or about May 10, 2007, Paul D. Goldenheim signed a plea agreement in Case No. 1:07CR00029.

64. PF denies the allegations contained in paragraph 64 of the Complaint, except admits that a report was issued by the United States General Accounting Office ("GAO") in December 2003 entitled "Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem," which speaks for itself as to its content.

65. PF denies the allegations contained in paragraph 65 of the Complaint, except admits that, on July 20, 2007, the Honorable James P. Jones accepted the plea agreements of The Purdue Frederick Company Inc., Howard R. Udell, Michael Friedman, and Paul D. Goldenheim and that, in addition to the sentences set forth in each plea agreement, which speak for themselves, Howard R. Udell, Michael Friedman, and Paul D. Goldenheim were sentenced to three years probation and four hundred hours of community service.

66. PF denies the allegations contained in paragraph 66 of the Complaint, except states that the Opinion and Order of the Honorable James P. Jones, entered July 23, 2007, in the Western District of Virginia in United States v. The Purdue Frederick Company, Inc. d/b/a The Purdue Frederick Company, et al., No. 1:07CR00029 speaks for itself as to its content.

67. PF denies each and every allegation contained in paragraph 67 of the Complaint.

68. In response to paragraph 68 of the Complaint, PF admits that the Abbott defendants provided limited and defined promotional assistance in the marketing of OxyContin pursuant to the Co-Promotion Agreement.

69. PF denies the allegations contained in paragraph 69 of the Complaint, except states that the Co-Promotion Agreement speaks for itself as to its content. PF further states that the decision in Steadfast Ins. Co. v. The Purdue Frederick Co., No. X08CV020191697S, 2004 WL 2166258 (Conn. Super. Sept. 1, 2004), referenced by plaintiff in paragraph 69 of the Complaint, speaks for itself as to its content.

70. In response to paragraph 70 of the Complaint, PF states that the December 2003 GAO report entitled "Prescription Drugs: OxyContin Abuse and Diversion and Efforts to Address the Problem" referenced in paragraph 70 speaks for itself as to its content.

71. PF denies the allegations contained in paragraph 71 of the Complaint, except states that the Co-Promotion Agreement speaks for itself as to its content.

72. PF denies each and every allegation contained in paragraph 72 of the Complaint.

73. PF denies the allegations contained in paragraph 73 of the Complaint, except states that OxyContin is, and generally has been, marketed in accordance with the package insert for OxyContin, except that, prior to July 2001, some employees of certain of the Purdue defendants made, or told other employees of certain of the Purdue defendants to make, certain statements about OxyContin to some healthcare professionals that were inconsistent with the package insert for OxyContin and the express warnings it contained about risks associated with

the medicine, which statements violated written company policies requiring adherence to the prescribing information.

74. PF denies each and every allegation contained in paragraph 74 of the Complaint, except states that OxyContin is, and generally has been, marketed in accordance with the package insert for OxyContin, except that, prior to July 2001, some employees of certain of the Purdue defendants made, or told other employees of certain of the Purdue defendants to make, certain statements about OxyContin to some healthcare professionals that were inconsistent with the package insert for OxyContin and the express warnings it contained about risks associated with the medicine, which statements violated written company policies requiring adherence to the prescribing information.

75. PF denies each and every allegation contained in paragraph 75 of the Complaint.

76. PF denies each and every allegation contained in paragraph 76 of the Complaint.

AS TO CLASS ACTION ALLEGATIONS

77. PF denies the allegations contained in paragraph 77 of the Complaint, except admits that plaintiff purports to bring this action as a class action and to define a putative class, but denies that plaintiff's claims are the proper subject of class certification.

78. PF denies the allegations contained in paragraph 78 of the Complaint, except admits that plaintiff purports to bring this action as a class action and to define a putative class, but denies that plaintiff's claims are the proper subject of class certification.

79. PF denies the allegations contained in paragraph 79 of the Complaint, except admits that plaintiff purports to bring this action as a class action, but denies that plaintiff's claims are the proper subject of class certification and specifically denies that plaintiff (and the putative class members) is entitled to any relief whatsoever.

80. PF denies the allegations contained in paragraph 80 of the Complaint, except admits that plaintiff purports to bring this action as a class action, but denies that plaintiff's claims are the proper subject of class certification.

81. PF denies the allegations contained in paragraph 81 of the Complaint, except admits that plaintiff purports to bring this action as a class action, but denies that plaintiff's claims are the proper subject of class certification.

82. PF denies the allegations contained in paragraph 82 of the Complaint, except admits that plaintiff purports to bring this action as a class action, but denies that plaintiff's claims are the proper subject of class certification.

83. PF denies the allegations contained in paragraph 83 of the Complaint, except admits that plaintiff purports to bring this action as a class action, but denies that plaintiff's claims are the proper subject of class certification.

84. PF denies the allegations contained in paragraph 84 of the Complaint, except denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations regarding the experience of plaintiff's counsel. Further, PF admits that plaintiff purports to bring this action as a class action, but denies that plaintiff's claims are the proper subject of class certification.

85. PF denies the allegations contained in paragraph 85 of the Complaint, except admits that plaintiff purports to bring this action as a class action, but denies that plaintiff's claims are the proper subject of class certification.

AS TO COUNT I

86. PF repeats and realleges its responses to paragraphs 1 through 85 of the Complaint, as if fully set forth herein.

87. PF denies each and every allegation contained in paragraph 87 of the Complaint.

88. PF denies each and every allegation contained in paragraph 88 of the Complaint.

89. PF denies each and every allegation contained in paragraph 89 of the Complaint.

90. PF denies each and every allegation contained in paragraph 90 of the Complaint.

91. PF denies each and every allegation contained in paragraph 91 of the Complaint.

92. PF denies each and every allegation contained in paragraph 92 of the Complaint.

93. PF denies each and every allegation contained in paragraph 93 of the Complaint.

94. PF denies each and every allegation contained in paragraph 94 of the Complaint.

95. PF denies each and every allegation contained in paragraph 95 of the Complaint.

96. PF denies each and every allegation contained in the first sentence of paragraph 96 of the Complaint. PF denies knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations contained in paragraph 96, except denies that plaintiff's claims are the proper subject of class certification.

97. PF denies each and every allegation contained in paragraph 97 of the Complaint.

98. PF denies each and every allegation contained in paragraph 98 of the Complaint.

99. PF denies each and every allegation contained in paragraph 99 of the Complaint.

100. PF denies each and every allegation contained in paragraph 100 of the Complaint.

101. PF denies each and every allegation contained in paragraph 101 of the Complaint.

102. PF denies each and every allegation contained in paragraph 102 of the Complaint, and specifically denies that plaintiff (and the putative class members) is entitled to any relief whatsoever.

AS TO COUNT II

103. PF repeats and realleges its responses to paragraphs 1 through 102 of the Complaint, as if fully set forth herein.

104. PF states that the statute referenced in paragraph 104 of the Complaint, 18 U.S.C. § 1962(d), speaks for itself as to its content.

105. PF denies each and every allegation contained in paragraph 105 of the Complaint.

106. PF denies each and every allegation contained in paragraph 106 of the Complaint.

107. PF denies each and every allegation contained in paragraph 107 of the Complaint.

108. PF denies each and every allegation contained in paragraph 108 of the Complaint.

109. PF denies each and every allegation contained in paragraph 109 of the Complaint.

110. PF denies each and every allegation contained in paragraph 110 of the Complaint.

111. PF denies each and every allegation contained in paragraph 111 of the Complaint.

112. PF denies each and every allegation contained in paragraph 112 of the Complaint, and specifically denies that plaintiff (and the putative class members) is entitled to any relief whatsoever.

AS TO COUNT III

113. PF repeats and realleges its responses to paragraphs 1 through 112 of the Complaint, as if fully set forth herein.

114. PF denies each and every allegation contained in paragraph 114 of the Complaint.

115. PF denies each and every allegation contained in paragraph 115 of the Complaint.

116. PF denies each and every allegation contained in paragraph 116 of the Complaint.

117. PF denies each and every allegation contained in paragraph 117 of the Complaint.

118. PF denies each and every allegation contained in paragraph 118 of the Complaint.

119. PF denies each and every allegation contained in paragraph 119 of the Complaint.

120. PF denies each and every allegation contained in paragraph 120 of the Complaint.

121. PF denies each and every allegation contained in paragraph 121 of the Complaint.

122. PF denies each and every allegation contained in paragraph 122 of the Complaint.

123. PF denies each and every allegation contained in paragraph 123 of the Complaint.

124. PF denies each and every allegation contained in paragraph 124 of the Complaint.

125. PF denies each and every allegation contained in paragraph 125 of the Complaint.

126. PF denies each and every allegation contained in paragraph 126 of the Complaint.

127. PF denies each and every allegation contained in paragraph 127 of the Complaint.

128. PF denies each and every allegation contained in paragraph 128 of the Complaint.

129. PF denies each and every allegation contained in paragraph 129 of the Complaint.

130. PF denies each and every allegation contained in paragraph 130 of the Complaint.

131. PF denies each and every allegation contained in paragraph 131 of the Complaint.

132. PF denies each and every allegation contained in paragraph 132 of the Complaint.

133. PF denies each and every allegation contained in paragraph 133 of the Complaint.

134. PF denies each and every allegation contained in paragraph 134 of the Complaint.

135. PF denies each and every allegation contained in paragraph 135 of the Complaint.

136. PF denies each and every allegation contained in paragraph 136 of the Complaint.

137. PF denies each and every allegation contained in paragraph 137 of the Complaint.

138. PF denies each and every allegation contained in paragraph 138 of the Complaint.

139. PF denies each and every allegation contained in paragraph 139 of the Complaint.

140. PF denies each and every allegation contained in paragraph 140 of the Complaint.

141. PF denies each and every allegation contained in paragraph 141 of the Complaint.

142. PF denies each and every allegation contained in paragraph 142 of the Complaint.

143. PF denies each and every allegation contained in paragraph 143 of the Complaint.

144. PF denies each and every allegation contained in paragraph 144 of the Complaint.

145. PF denies each and every allegation contained in paragraph 145 of the Complaint.

146. PF denies each and every allegation contained in paragraph 146 of the Complaint.

147. PF denies each and every allegation contained in paragraph 147 of the Complaint.

148. PF denies each and every allegation contained in paragraph 148 of the Complaint.

149. PF denies each and every allegation contained in paragraph 149 of the Complaint.

150. PF denies each and every allegation contained in paragraph 150 of the Complaint.

151. PF denies each and every allegation contained in paragraph 151 of the Complaint.

152. PF denies each and every allegation contained in paragraph 152 of the Complaint.

153. PF denies each and every allegation contained in paragraph 153 of the Complaint.

154. PF denies each and every allegation contained in paragraph 154 of the Complaint.

155. PF denies each and every allegation contained in paragraph 155 of the Complaint.

156. PF denies each and every allegation contained in paragraph 156 of the Complaint.

157. PF denies each and every allegation contained in paragraph 157 of the Complaint.

158. PF denies each and every allegation contained in paragraph 158 of the Complaint.

159. PF denies each and every allegation contained in paragraph 159 of the Complaint.

160. PF denies each and every allegation contained in paragraph 160 of the Complaint.

161. PF denies each and every allegation contained in paragraph 161 of the Complaint.

162. PF denies each and every allegation contained in paragraph 162 of the Complaint.

163. PF denies each and every allegation contained in paragraph 163 of the Complaint.

164. PF denies each and every allegation contained in paragraph 164 of the Complaint.

165. PF denies each and every allegation contained in paragraph 165 of the Complaint.

166. PF denies each and every allegation contained in paragraph 166 of the Complaint, and specifically denies that plaintiff (and the putative class members) is entitled to any relief whatsoever.

AS TO COUNT IV

167. PF repeats and realleges its responses to paragraphs 1 through 166 of the Complaint, as if fully set forth herein.

168. PF denies each and every allegation contained in paragraph 168 of the Complaint.

169. PF denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 169 of the Complaint, except denies that plaintiff's claims are the proper subject of class certification.

170. PF denies each and every allegation contained in paragraph 170 of the Complaint.

171. PF denies each and every allegation contained in paragraph 171 of the Complaint, and specifically denies that plaintiff (and the putative class members) is entitled to any relief whatsoever.

AS TO THE DEMAND FOR RELIEF

In response to the "WHEREFORE" clause located on pages 42-43 of the Complaint, PF denies that plaintiff (and the putative class members) is entitled to any relief whatsoever.

PF denies each and every allegation not heretofore specifically admitted.

AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE

This Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiff (and the putative class members) lacks standing to assert some or all of the claims asserted in the Complaint.

THIRD AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred, in whole or in part, on the ground of remoteness.

FOURTH AFFIRMATIVE DEFENSE

The injuries and damages claimed by plaintiff (and the putative class members) were caused, in whole or in part, by actions or omissions of others for whose conduct PF is not responsible.

FIFTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred, in whole or in part, to the extent that the proximate cause of any alleged injury was plaintiff's (and the putative class members') members' choice to use, misuse, or abuse OxyContin in a manner other than that recommended. The intervening or superseding cause of any injury allegedly sustained by plaintiff's (and the putative class members') accordingly would be plaintiff's (and the putative class members') members' own conduct.

SIXTH AFFIRMATIVE DEFENSE

The intervening or superseding cause of any injury allegedly sustained by plaintiff's (and the putative class members') members may be conduct which is illicit, criminal or otherwise improper, and for which PF cannot be held responsible.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred, in whole or in part, by the doctrines of laches, waiver, estoppel and unclean hands.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred, in whole or in part, by the doctrine of assumption of risk.

NINTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') causes of action and claims may not properly be maintained or certified as a class action.

TENTH AFFIRMATIVE DEFENSE

The certification of this action as a class action would violate PF's right to a separate jury trial on the issue of liability as provided in the Seventh Amendment to the United States Constitution and the laws of the State of New York.

ELEVENTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred, in whole or in part, to the extent plaintiff's (or the putative class members') members were prescribed OxyContin for medical purposes other than those for which OxyContin has been approved by the FDA.

TWELFTH AFFIRMATIVE DEFENSE

The product at issue, OxyContin, was approved pursuant to the applicable statutes and regulations. The labeling for OxyContin was also approved by the FDA. Such actions and federal regulations and statutes preempt plaintiff's (and the putative class members') claims under state law.

THIRTEENTH AFFIRMATIVE DEFENSE

The doctrine of primary jurisdiction bars the claims of plaintiffs (and the putative class members). The FDA has primary jurisdiction over the issues raised in the Complaint. The FDA, pursuant to federal law, has exclusive regulatory control of products such as the product at issue here. Therefore, this Court should defer any consideration of the issues raised in the Complaint which are properly within the purview of the FDA and refer such issues to that agency for determination.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred, in whole or in part, by the applicable statutes of limitation.

FIFTEENTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred, in whole or in part, by the contributory and comparative negligence of plaintiff's (and the putative class members') members.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') recovery is barred, in whole or in part, to the extent that plaintiff (and the putative class members') or plaintiff's (and the putative class members') members failed to mitigate the alleged injuries or damages.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred, in whole or in part, to the extent that plaintiff's (and the putative class members') members consented to the acts alleged in the Complaint.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred to the extent that those claims are based on an alleged duty to warn of risks associated with the use of OxyContin, inasmuch as plaintiff's (and the putative class members') members were warned or were otherwise made aware of alleged dangers of the product, and further, any such alleged dangers were not beyond that which would have been contemplated by the ordinary consumer of the product with the ordinary knowledge common to the community.

NINETEENTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred, in whole or in part, because the design, inspection, packaging, and/or labeling of OxyContin are, and have always been, consistent with the generally recognized technological, medical, scientific, and industrial state-of-the art.

TWENTIETH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred because statements, promotions, and advertisements of OxyContin are protected by the First Amendment of the United States Constitution and the correlative provisions of the New York Constitution and any other applicable state constitutions.

TWENTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff (and the putative class members) is barred from recovering any damages by virtue of the fact that the dangers, if any, claimed by plaintiff (and the putative class members) were open and obvious.

TWENTY-SECOND AFFIRMATIVE DEFENSE

If the product allegedly involved in this action was defective or unreasonably dangerous, which PF denies, plaintiff's (and the putative class members') members were aware thereof and unreasonably proceeded to make use of the product in that condition.

TWENTY-THIRD AFFIRMATIVE DEFENSE

PF states that all OxyContin lawfully sold or distributed in the United States carries warnings which adequately informed plaintiff's (and the putative class members') members of any alleged health risks of using OxyContin.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

PF states that plaintiff and plaintiff's (and the putative class members') members did not justifiably rely on the activities attributed by plaintiffs to PF in the Complaint, and that any injuries or damages complained of in the Complaint were not caused by PF's alleged actions.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred to the extent that the injuries alleged in the Complaint resulted from any person's preexisting and/or unrelated medical or psychiatric condition and/or idiosyncratic reaction to OxyContin. In the alternative, the alleged damages must be reduced to the extent that they were caused or enhanced by a preexisting and/or unrelated medical or psychiatric condition and/or idiosyncratic reaction to OxyContin of persons on whose behalf plaintiff (and the putative class members) made payments for OxyContin.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members) claimed damages are too speculative to form the basis for relief.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

While denying that plaintiff (and the putative class members) or plaintiff's (and the putative class members') members suffered any injury for which PF is liable, PF avers that any injuries suffered by plaintiff (and the putative class members) or plaintiff's (and the putative class

members') members have been mitigated, in whole or in part, by reimbursement from collateral sources.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred by the learned intermediary doctrine.

TWENTY-NINTH AFFIRMATIVE DEFENSE

Plaintiff (and the putative class members) is barred from recovering any damages by virtue of the fact that any harm caused by OxyContin was caused by an inherent aspect of the product which could not be eliminated without compromising its usefulness.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred, in whole or in part, if plaintiff's (and the putative class members') members altered or modified the OxyContin tablets and ingested them in a manner other than that described in OxyContin's instructions for use.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims are barred, in whole or in part, because plaintiff (and the putative class members) and plaintiff's (and the putative class members') members lack privity with PF.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiff (and the putative class members) is barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by plaintiff (or the putative class members) without substantially impairing its usefulness or intended purpose of the product.

THIRTY-THIRD AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') claims violate the due process provisions of the United States Constitution and the correlative provisions of the New York Constitution to and any other applicable state constitutions to the extent that they seek to deprive PF of the procedural and substantive safeguards, including traditional defenses to liability.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiff's (and the putative class members') fraud and misrepresentation-based claims are not stated with particularity as required by the applicable rules of civil procedure.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

To the extent that the laws of other jurisdictions apply, PF invokes each and every constitutional defense available to it under the constitutions (or similar charters) of each of the other forty-nine states, the District of Columbia, the Commonwealth of Puerto Rico, and the territories and possessions of the United States. This specifically includes, but is not limited to, provisions relating to due process, access to the courts, freedom of speech, freedom of

association, freedom to petition the government for redress of grievances, and limitations on damages.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

To the extent that the laws of other jurisdictions apply, PF invokes each and every statutory and common law defense available to it under the laws of each of the other forty-nine states, the District of Columbia, the Commonwealth of Puerto Rico, and the territories and possessions of the United States with respect to each of the claims alleged in the Complaint that is recognized in that jurisdiction.

PF adopts and incorporates by reference any affirmative defense asserted by any other defendant to this action, to the extent such affirmative defense applies to PF. PF reserves the right to assert, and hereby gives notice that it intends to rely upon, any other defense that may become available or appear during discovery proceedings or otherwise in this case and hereby reserves the right to amend its answer to assert any such defense.

WHEREFORE, PF respectfully requests that the Court dismiss the Complaint in its entirety with prejudice and award PF its costs and disbursements, including attorneys' fees, incurred in defending this action together with such other relief as this court deems just and proper.

JURY DEMAND

PF demands a jury trial on all issues so triable.

Dated: October 9, 2007

CHADBOURNE & PARKE LLP

By  

Donald I. Strauber
Mary T. Yelenick
Phoebe A. Wilkinson

Attorneys for The Purdue Frederick
Company Inc.
30 Rockefeller Plaza
New York, New York 10112
(212) 408-5100

KING & SPALDING
Chilton Davis Varner
Gordon A. Smith
1180 Peachtree Street, NE
Atlanta, GA 30309
Tel: (404) 572-4600

COVINGTON & BURLING
Timothy C. Hester
Patrick S. Davies
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401
Tel: (202) 662-5274